K023498

NOV 13 2002

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Firm:	Blackstone Medical, Inc. 90 Brookdale Drive Springfield, MA 01104
510(k) Contact:	Dean E. Ciporkin Director, Regulatory Affairs and Quality Assurance
Trade Name:	Blackstone™ Spinal Fixation System Spinal Fixation System Multi-Axial Screws
Common Name:	Rod and screw spinal instrumentation
Device Product Code & Classification:	**MNH** – 888.3070 – Spondylolisthesis Spinal Fixation Device System **KWQ** - 888.3060 - Spinal Intervertebral Body Fixation Orthosis **MNI** – 888.3070 – Pedicle Screw Spinal System
Substantially Equivalent Devices:	Blackstone™ Spinal Fixation System (K994217) Blackstone™ Spinal Fixation System 4.5mm Multi-Axial Screws (K020674)

Device Description:

The Blackstone™ Spinal Fixation System 4.5mm, 5.5mm, 6.5mm, and 7.5mm Multi-Axial Screws are titanium alloy (6AL-4V ELI, per ASTM F136) devices, which are non-sterile, single use components that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws to the non-cervical spine.

The Blackstone Spinal Fixation System consists of an assortment of screws and rods which have received 510(k) clearance (#K994217, and #K020674).

Intended Use / Indications for Use:

The Blackstone Spinal Fixation System is intended for non-cervical use in the spine. The Blackstone Spinal Fixation System, when used for pedicle screw fixation, is intended only for patients:

a) Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;

b) Who are receiving fusion using autogenous bone graft only;
c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and
d) Who are having the device removed after the development of a solid fusion mass.

The Blackstone Spinal Fixation System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:
a) Degenerative spondylolistheses with objective evidence of neurologic impairment;
b) Fracture;
c) Dislocation;
d) Scoliosis;
e) Kyphosis;
f) Spinal tumor; and
g) Failed previous fusion (pseudarthrosis).

The Blackstone Spinal Fixation System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:
a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
b) spondylolistheses;
c) spinal stenosis;
d) spinal deformities (i.e., scoliosis, kyphosis, lordosis);
e) tumor;
f) pseudoarthrosis;
g) previous failed fusion; and
h) trauma (i.e., fracture or dislocation).

The Blackstone Spinal Fixation System, when used for posterior non-pedicle screw fixation system of the non-cervical spine, is intended for the following indications:
a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
b) spondylolistheses;
c) spinal stenosis;
d) spinal deformities (i.e., scoliosis, kyphosis, lordosis);
e) tumor;
f) pseudoarthrosis;
g) previous failed fusion; and
h) trauma (i.e., fracture or dislocation).

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Blackstone™ 4.5mm, 5.5mm, 6.5mm, and 7.5mm Multi-Axial Screws by their very nature are substantially equivalent to the DePuy Motech Moss Miami Spinal

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System (K980477, K982320) which has been cleared by FDA for certain anterior and pedicle fixation use indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Dean E. Ciporkin
Director, Regulatory Affairs and Quality Assurance
Blackstone Medical, Inc.
90 Brookdale Drive
Springfield, Massachusetts 01104

Re: K023498
Trade/Device Name: Blackstone Spinal Fixation System
Regulation Number: 21 CFR 888.3050, 888.3060, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis; Spinal intervetebral body fixation orthosis; Spondylolisthesis spinal fixation device system; Pedicle screw spinal system
Regulatory Class: Class II
Product Code: KWP, KWQ, MNH, MNI
Dated: October 14, 2002
Received: October 18, 2002

Dear Mr. Ciporkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

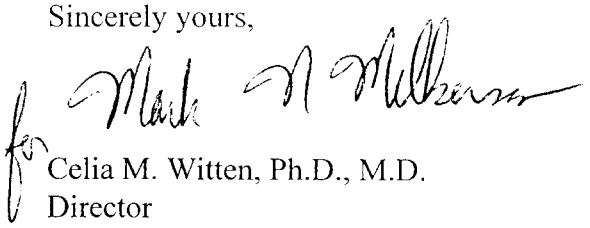
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K023498

Device Name: *Blackstone™ Spinal Fixation System*

Indications for Use:

The Blackstone Spinal Fixation System is intended for non-cervical use in the spine. The Blackstone Spinal Fixation System, when used for pedicle screw fixation, is intended only for patients:

a) Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;
b) Who are receiving fusion using autogenous bone graft only;
c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and
d) Who are having the device removed after the development of a solid fusion mass.

The Blackstone Spinal Fixation System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

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b) Fracture;
c) Dislocation;
d) Scoliosis;
e) Kyphosis;
f) Spinal tumor; and
g) Failed previous fusion (pseudarthrosis).

The Blackstone Spinal Fixation System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
b) spondylolistheses;
c) spinal stenosis;
d) spinal deformities (i.e., scoliosis, kyphosis, lordosis);
e) tumor;
f) pseudoarthrosis;
g) previous failed fusion; and
h) trauma (i.e., fracture or dislocation).

The Blackstone Spinal Fixation System, when used for posterior non-pedicle screw fixation system of the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
b) spondylolistheses;

for Mark N. Milleson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices
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c) spinal stenosis;
d) spinal deformities (i.e., scoliosis, kyphosis, lordosis);
e) tumor;
f) pseudoarthrosis;
g) previous failed fusion; and
h) trauma (i.e., fracture or dislocation).

Concurrence of CDRH, Office of device Evaluation

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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Prescription Use_____ OR Over-The-Counter Use_____

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